

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Joerg Schneider, Sarah C. Gilbert, Carolyn M. Hannan and Adrian V.S. Hill

Application No.: 10/088,677

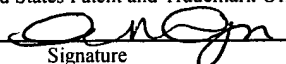
Group Art Unit: 1645

371(c) Date: May 31, 2002

Examiner: Robert A. Zeman

Confirmation No.: 4825

Title: USE OF REPLICATION-DEFICIENT ADENOVIRAL VECTOR TO BOOST  
CD8+T CELL IMMUNE RESPONSE TO ANTIGEN

CERTIFICATE OF MAILING OR TRANSMISSION	
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☒ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☒ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application file.  
(Filed after payment of issue fee)

08/01/2006 WAB/ELR1 00000042 10088677 180.00 0P  
02 FC:1806

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed.
    - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for reference [C30] under 37 CFR 1.98(a)(3) is satisfied by:
  - ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☒ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:  
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. 60/148,981, by Ling Chen, John Shiver, Andrew Bett, Danilo Riguera Casimiro, Michael J. Caulfield, Michael A. Chastain and Emilio A. Emini, filed August 13, 1999.

\_\_\_\_ U.S. Patent Application No. 60/150,728, by Michael P. Neeper, William L. McClements, Kathrin U. Jansen, Loren D. Schultz, Ling Chen and Xin-Min Wang, filed August 25, 1999.

\_\_\_\_ U.S. Patent Application No. 60/680,838, by Andrew McMichael, Adrian V.S. Hill, Sarah C. Gilbert, Joerg Schneider, Magdalena Plebanski, Thomas Hanke, Geoffrey L. Smith, Tom Blanchard, an Martin Cripps, filed May 13, 2005, Docket No.: 3022.1002-000.

\_\_\_\_ U.S. Patent Application No. 60/683,877, by Adrian V.S. Hill, Sarah C. Gilbert, Joerg Schneider, and Geoffrey L. Smith, filed May 23, 2005, Docket No.: 3022.1003-000.

\_\_\_\_ U.S. Patent Application No. 60/782,710, by Joerg Schneider, Jamie Chorlton, Gill Pearce, Nicola Jones and Dean Brown, filed March 15, 2006, Docket No.: 3022.1003-001.

\_\_\_\_ Examiner

\_\_\_\_ Date

- [X] A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- [ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [X] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: July 26, 2006

APPLICATION NO.  
10/088,677

**SECOND SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT IN AN APPLICATION**

FIRST NAMED INVENTOR  
Joerg Schneider

FILING DATE  
May 31, 2002

**July 25, 2006**

EXAMINER  
Robert A. Zeman

CONFIRMATION NO.  
4825

GROUP  
1645

JUL 3 1 2006

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

[illegible]

EXAMINER

DATE CONSIDERED

APPLICATION NO.  
10/088,677

## SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

**July 25, 2006**

(Use several sheets if necessary)

FIRST NAMED INVENTOR  
Joerg Schneider

FILING DATE  
May 31, 2002

EXAMINER  
Robert A. Zeman

CONFIRMATION NO.  
4825

GROUP  
1645

## FOREIGN PATENT DOCUMENTS

[illegible]

EXAMINER

DATE. CONSIDERED

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
3022.1004-000APPLICATION NO.  
10/088,677SECOND SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT IN AN APPLICATION

July 25, 2006

FIRST NAMED INVENTOR  
Joerg SchneiderFILING DATE  
May 31, 2002EXAMINER  
Robert A. ZemanCONFIRMATION NO.  
4825GROUP  
1645

JUL 31 2006

(Use several sheets if necessary)

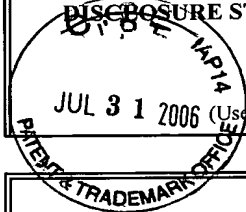
## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C1	Anderson, <i>et al.</i> , "Enhanced CD8 T Cell Response and Protective Efficacy Against Malaria Using Recombinant Fowlpox Virus In Heterologous Prime/Boost Immunisation Regimes," Abstract, <i>Immunology 101</i> (Supplement 1):32 (2000).
C2	Berkner, K.L., "Development of Adenovirus Vectors For The Expression of Heterologous Genes," <i>BioTechniques</i> , 6(7): 616-629, (1988).
C3	Buge, S.L., <i>et al.</i> , "Factors Associated With Slow Disease Progression in Macaques Immunized With an Adenovirus-Simian Immunodeficiency Virus (SIV) Envelope Priming-gp120 Boosting Regimen and Challenged Vaginally With SIVmac251," <i>Journal of Virology</i> , 73(9):7430-7440, (1999).
C4	Chamberlain, R.S., Poster Presentation presented at the Meeting of the American Association of Cancer Research, April 20 <sup>th</sup> through April 24 <sup>th</sup> , 1996.
C5	Chamberlain, R.S., <i>et al.</i> , "Use of Multiple Vaccination Vectors for the Generation of CTL Against a Model Tumor Antigen," <i>Proceedings of the Annual Meeting of the American Association for Cancer Research</i> (Washington, April 20-24, 1996, 37, Abstract No. 3263).
C6	E-mail from American Society for Microbiology re: Date of Disclosure of Buge's Document.
C7	Hanke, T., <i>et al.</i> , "Enhancement of MHC Class I-Restricted Peptide-Specific T Cell Induction by a DNA Prime/MVA Boost Vaccination Regime," <i>Vaccine</i> , 16(5):439-445, (1998).
C8	Hodge, J.W., <i>et al.</i> , "Diversified Prime and Boost Protocols Using Recombinant Vaccinia Virus and Recombinant Non-Replicating Avian Pox Virus to Enhance T-Cell Immunity and Antitumor Responses," <i>Vaccine</i> 15(6/7):759-768 (April/May 1997).
C9	Irvine, K.R., <i>et al.</i> , "Enhancing Efficacy of Recombinant Anticancer Vaccines With Prime/Boost Regimens That Use Two Different Vectors," <i>Journal of the National Cancer Institute</i> , 89(21):1595-1601, (1997).
C10	Kent, S. J., <i>et al.</i> , "Enhanced T-Cell Immunogenicity and Protective Efficacy of a Human Immunodeficiency Virus Type 1 Vaccine Regimen Consisting of Consecutive Priming with DNA and Boosting with Recombinant Fowlpox Virus," <i>J. Virol.</i> 72(12):10180-10188 (1998).
C11	Li, Shengqiang, <i>et al.</i> , "Priming With Recombinant Influenza Virus Followed By Administration of Recombinant Vaccinia Virus Induces CD8 <sup>+</sup> T-Cell-Mediated Protective Immunity against Malaria," <i>Proc. Natl. Acad. Sci. USA</i> 90(11):5214-5218 (June 1993).

EXAMINER

DATE CONSIDERED


UPTO-1449 REPRODUCED  <b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  July 25, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3022.1004-000	APPLICATION NO. 10/088,677	
	FIRST NAMED INVENTOR Joerg Schneider		FILING DATE May 31, 2002
	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645



**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

C12	McShane, H., <i>et al.</i> , "Enhanced Immunogenicity of CD4 <sup>+</sup> T-Cell Responses and Protective Efficacy of a DNA-Modified Vaccinia Virus Ankara Prime-Boost Vaccination Regimen for Murine Tuberculosis," <i>Infect. Imm.</i> 69(2):681-686 (2001).
C13	Notice of Opposition to a European Patent. Patent No.: EP 1214416B1. Opponent: Merck & Co., Inc.
C14	Notice of Opposition to a European Patent. Patent No.: EP 1214416B1. Opponent: Crucell Holland B.V.
C15	Notice of Opposition to a European Patent. Patent No.: EP 1214416. Opponent: Transgene S.A. (English translation attached)
C16	Plebanski, M., <i>et al.</i> , "Protection From <i>Plasmodium berghei</i> Infection By Priming and Boosting T Cells to a Single Class I-Restricted Epitope with Recombinant Carriers Suitable for Human Use," <i>Eur. J. Immunol.</i> , 28(12):4345-4355 (1998).
C17	Reece, WHH, <i>et al.</i> , "A DNA/MVA Prime-Boost Vaccination Regime Induces Strong Immune Responses and Partial Protection Against <i>Plasmodium falciparum</i> in Humans," <i>Poster at the British Society for Immunology</i> (December 2001).
C18	Richmond, J.F.L., <i>et al.</i> , "Screening of HIV-1 Env Glycoproteins for the Ability to Raise Neutralizing Antibody Using DNA Immunization and Recombinant Vaccinia Virus Boosting," <i>Virology</i> 230:265-274 (1997).
C19	Robert-Guroff, M., <i>et al.</i> , "Vaccine Protection Against a Heterologous, Non-Syncytium-Inducing, Primary Human Immunodeficiency Virus," <i>Journal of Virology</i> , 72(12):10275-10280, (1998).
C20	Robinson, H. L., <i>et al.</i> , "Neutralizing Antibody-independent Containment of Immunodeficiency Virus Challenges by DNA Priming and Recombinant Pox Virus Booster Immunizations," <i>Nature Medicine</i> 5(5):526-534 (1999).
C21	Rodrigues, E.G., <i>et al.</i> , "Efficient Induction of Protective Anti-Malaria Immunity By Recombinant Adenovirus," <i>Vaccine</i> , 16(19):1812-1817, (1998).
C22	Rodrigues, E.G., <i>et al.</i> , "Single Immunizing Dose of Recombinant Adenovirus Efficiently Induces CD8 <sup>+</sup> T Cell-Mediated Protective Immunity Against Malaria," <i>The Journal of Immunology</i> , 158:1268-1274, (1997).

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED  <b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>   July 25, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3022.1004-000	APPLICATION NO. 10/088,677	
	FIRST NAMED INVENTOR Joerg Schneider		FILING DATE May 31, 2002
	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

C23	Schneider, J., <i>et al.</i> , "Induction of CD8 <sup>+</sup> T Cells Using Heterologous Prime-Boost Immunisation Strategies," <i>Immunology Reviews</i> , 170:29-38, (1999).
C24	Schneider, J., <i>et al.</i> , "A Prime-Boost Immunisation Regimen Using DNA Followed By Recombinant Modified Vaccinia Virus Ankara Induces Strong Cellular Immune Responses Against the <i>Plasmodium falciparum</i> TRAP Antigen In Chimpanzees," <i>Vaccine</i> , 19(32):4595-4602 (2001).
C25	Shah, K.V. and Howley, P.M., "Papillomaviruses," <i>Fields Virology, Third Edition, Chapter 66</i> , pp. 2077-2109, (1996).
C26	The Chamberlain Declaration cited in the opposition proceedings of European Patent Application No. EP0979284.
C27	The Gritz Declaration cited in the opposition proceedings of European Patent Application No. EP0979284.
C28	The Schlom Declaration cited in the opposition proceedings of European Patent Application No. EP0979284.
C29	Timofeev, A.V., <i>et al.</i> , "Immunological Basis For Protection In A Murine Model of Tick-Borne Encephalitis By a Recombinant Adenovirus Carrying the Gene Encoding the NS1 Non-Structural Protein," <i>Journal of General Virology</i> , 79:689-695, (1998).
C30	Timofeyev, A.V., <i>et al.</i> , "Recombinant Adenovirus Expressing The NS1 Nonstructural Protein of Tick-Borne Encephalitis Virus: Characteristics of Immunological Basis of Antiviral Effect," <i>Vopr. Virusol.</i> 42:219-222, (1997).
C31	Xiang, Z.Q., <i>et al.</i> , "Induction of Genital Immunity by DNA Priming and Intranasal Booster Immunization With a Replication-Defective Adenoviral Recombinant," <i>The Journal of Immunology</i> , 162: 6716-6723, (1999).

EXAMINER	DATE CONSIDERED
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